

**IN THE U.S. PATENT AND TRADEMARK OFFICE**

In re application of

Tomas FABO

Conf. 9965

Application No. 10/553,953

Group 1611

Filed June 12, 2006

Examiner Kevin Orwig

ELASTOMER-FORMING BARRIER PREPARATION

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

September 21, 2009

Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this request.

A Notice of Appeal is filed herewith.

The review is requested for the reasons advanced on the attached sheets.

Respectfully submitted,

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**REASONS IN SUPPORT OF REQUEST FOR REVIEW**

A pre-appeal brief review is respectfully requested because the ground of rejection maintained in the Final Official Action of May 19, 2009 (herein "Final Action") includes at least one clear legal and at least one factual error.

There are two grounds of rejection for review:

The first ground is whether claims 9, 10 and 14 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over GUYURON et al. U.S. 6,471,985 (GUYURON).

The second ground is whether claims 9, 11-13, 15, 16, 19 and 20 were properly rejected under 35 USC 103(a) as being unpatentable over GUYURON in view of ABBER et al. U.S. 4,925,671 (ABBER).

**I. The first ground of rejection includes a factual error.**

Independent claim 9 is directed to a method of applying a protective layer to non-wounded skin (stratum corneum) comprising applying a preparation which adheres to non-wounded skin, and allowing the preparation to cure to form an elastomer which adheres to the non-wounded skin. The present specification (at page 16, lines 30-34) describes that the risk for the preparation to spread into the wound is reduced. Thus in view of the claimed language and the specification, it is clear that the claimed method applies the preparation to non-wounded skin.

GUYURON teaches a method of treating wounds utilizing a room temperature vulcanizing (RTV) silicone composition. The

rejection is based on the following assumption, as explained in the paragraph bridging pages 3 and 4 of the Official Action:

"Since an object of Guyuron's invention is to prevent infection of the wound (col. 1, lines 19-23 and 62-63; col. 2, lines 49 and 58), an ordinary artisan would understand Guyuron's teachings to mean that the silicone composition is applied over a wound, including the surrounding non-wounded skin as is typical of methods aiming to prevent infection by sealing a wound in order to prevent the entrance of bacteria or other contaminants."

**a. There is no explicit teaching of applying a protective layer to non-wounded skin.**

The disclosure of GUYURON is limited to applying a composition to a wound.

For example, GUYURON discloses treating wounds by applying a composition over the wounds. See, e.g., column 1, lines 6-8. The claims of GUYURON are limited to applying the composition to a wound.

In describing the prior art, GUYURON states "Wound dressings must adhere to a wound, yet possess releaseability characteristics enabling a non-damaging removal from the wound." See, e.g., column 1, lines 25-28. Moreover, GUYURON discloses, in column 11, lines 6-9, "The RTV silicone composition may be custom fit to any contoured or shaped surface. This advantage over and in contrast with prefabricated bandaids or dressings, or dressings that must be cut and fit to a wound." (Emphasis added.)

Thus, the invention of GUYURON and even the relevant prior art discussed by GUYURON are solely focused on application

to the wound itself. There is no mention of the non-wounded skin (stratum corneum).

**b. There is no implicit teaching of  
applying a protective layer to non-wounded skin.**

The conclusion on page 8, first paragraph of the Official Action states, "there would be at least some amount of wounded tissue left unprotected between the composition and the non-wounded skin". The support cited was column 1, lines 59 and 60 of GUYURON.

However, this passage cited in support of the conclusion merely states that the silicone adequately adheres to a wound, but says nothing about adherence to skin.

Moreover, GUYURON discloses that the advantage of applying the composition in a highly viscous state makes it possible to cover the whole wound bed. This is done without having to apply the composition to non-wounded skin surrounding the wound bed.

Even if some composition unintentionally reached outside the wound bed, this contact would not teach the claimed method of applying a protective layer to non-wounded skin (stratum corneum), e.g., comprising applying a preparation which adheres to non-wounded skin, and allowing the preparation to cure to form an elastomer which adheres to the non-wounded skin, as recited in independent claim 9. Nor would this contact suggest applying around a wound, immediately outside the edge of the wound as recited in dependent claim 14.

**II. The first ground of rejection includes a legal error.**

One of ordinary skill in the art would have been discouraged from modifying GUYURON as claimed.

GUYURON, as discussed above, discloses that the composition "may be custom fit to any contoured or shaped surface", and the advantage over the prior art is that the dressings do not have to be cut and fit to a wound.

GUYURON requires that the composition forms a membrane over the wound to retain moisture in the wound. See, e.g., Column 11, lines 15-18.

Thus, application of a protective layer to non-wounded skin (stratum corneum) as recited in claim 9, and most certainly around the wound itself in claim 14, would have rendered the composition GUYURON unsatisfactory for its intended purpose of fitting the wound and providing moisture retention.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

**II. The second ground of rejection includes a legal error.**

The position was that one would have envisioned the use of the composition taught by GUYURON as adhesives for the use suggested by ABBER.

However, to the contrary, one would have been discouraged from using the GUYURON adhesive with ABBER devices.

ABBER discloses specific devices that require adhesives with very specific characteristics: favorable adhesive, shear, liquid permeability and release characteristics.

As the adhesive of GUYURON retains moisture when placed over a wound (column 11, lines 15-18), the adhesive would have rendered the ABBER devices requiring liquid permeability unsatisfactory for their intended purpose.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

### **Conclusion**

In view of the least one clear legal error and at least three clear factual errors discussed above, the rejection should be withdrawn and this application allowed.